

**Joint Arrangements for Research**

**Adverse Event report - Medical Device**

<b>What are you reporting?</b>		
SAE / SADE <input type="checkbox"/>	USADE <input type="checkbox"/> *	
<i>*If the event is related and unanticipated it is an Unexpected Serious Adverse Device Event (USADE) and requires expedited reporting. Inform the Sponsor immediately.</i>		
Is the Study Device Blinded or Unblinded? Blinded <input type="checkbox"/> Unblinded <input type="checkbox"/>		
Has the subject been unblinded? Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>		
Was the event related to a protocol violation? Yes <input type="checkbox"/> No <input type="checkbox"/>		
Was the subject withdrawn due to this event? Yes <input type="checkbox"/> No <input type="checkbox"/>		
<b>Report Type:</b>	Initial Report <input type="checkbox"/> Follow-up Report <input type="checkbox"/> Final Report <input type="checkbox"/>	
<b>Study information</b>		
<b>Study Title: (short)</b>		
<b>Sponsor:</b>	<b>Chief Investigator Name:</b>	
	<b>Email Address:</b>	
<b>EUDAMED - ID:</b>	<b>R&amp;D Reference Number / IRAS Number:</b>	
<b>Clinical Investigation Plan title and version number:</b>		
<b>Site Number:</b> <i>(for multi-site studies only)</i>	<b>Site Name:</b>	
<b>Principal Investigator</b>	<b>Name:</b>	
	<b>Email address:</b>	
<b>Date of site becoming aware of the event (dd/mm/yy):</b>		
<b>Participant information</b>		
<b>Participant DOB:</b> <i>(dd/mm/yy)</i>	<b>Participant initials:</b>	<b>Participant Gender:</b> <input type="checkbox"/> Male <input type="checkbox"/> Female
<b>Participant Randomisation No:</b>		

Evaluation of Event	
<b>Event/Reaction:</b> <i>(keywords; e.g. body site, symptoms, severity, treatment)</i>	
<b>Date of onset:</b> <i>(dd/mm/yy)</i>	<b>Date person completing form became aware of event:</b> <i>(dd/mm/yy)</i>
<b>Criteria for definition as SAE *:</b> <input type="checkbox"/> Congenital abnormality/birth defect <input type="checkbox"/> Resulted in death <input type="checkbox"/> Life threatening <input type="checkbox"/> In patient hospitalisation/prolongation of hospitalisation <input type="checkbox"/> Persistent or significant disability <input type="checkbox"/> other e.g. is otherwise considered medically significant by the investigator <i>* If there is more than one criterion, choose the more/most significant one.</i>	
<b>Describe event:</b> <i>(A summary of signs and symptoms, diagnosis, treatment of event, concurrent treatment, other relevant medical history, including re-challenge details if applicable. Please include the point in the study at which the event occurred.)</i>	
<b>In the investigators opinion was the event related to a research procedure?</b>	<input type="checkbox"/> Definitely <input type="checkbox"/> Likely <input type="checkbox"/> Possibly <input type="checkbox"/> Unlikely <input type="checkbox"/> Not related
<b>Please specify which procedure if applicable</b>	

**Study Medical Device Information:** If more than one device is being used, please complete for each device

**Subject has been fitted / used / treated with the device?** Yes  No

If No - Give Reason (i.e. screening)

If Yes, provide details in the table below:

Name of Device	Indication for use	Route of administration / use	Date of first use	Date of last use

<b>In the investigators opinion was the event related to the device?</b>	<input type="checkbox"/> Definitely <input type="checkbox"/> Likely <input type="checkbox"/> Possibly <input type="checkbox"/> Unlikely <input type="checkbox"/> Not related	
<b>Action taken with Device</b>	<input type="checkbox"/> None <input type="checkbox"/> Device schedule adjusted <input type="checkbox"/> Device Permanently Removed/Discontinued Date: <input type="checkbox"/> Other – provide details Detail treatment given: <input type="checkbox"/> Unknown at time of report <input type="checkbox"/> Not applicable	
<b>If related to the device was this reaction unexpected (Unexpected Serious Adverse Device Event – USADE)?</b>		
<input type="checkbox"/> Yes..... <input type="checkbox"/> No <input type="checkbox"/> Not applicable		
<b>Outcome of event</b>		
<b>What is the outcome of the SAE?</b>	<b>Date event resolved:</b> (dd/mm/yy)	<b>Date patient died:</b> (dd/mm/yy)

<input type="checkbox"/> Recovered <input type="checkbox"/> Recovered with Sequelae <input type="checkbox"/> Continuing <input type="checkbox"/> Resulted in death <input type="checkbox"/> Unknown		
<b>Cause of death obtained from:</b>	<input type="checkbox"/> Coroner's inquest <input type="checkbox"/> Death certificate <input type="checkbox"/> Working diagnosis	
<b>Contact and signatures</b>		
<p><b>Please supply contact details where further information may be obtained:</b></p> <p><b>Person to contact:</b></p> <p><b>Phone number:</b></p> <p><b>Email address:</b></p>		

\_\_\_\_\_  
**Signature** *(person completing report)*

**Print name**

**Date** *(dd/mm/yy)*

\_\_\_\_\_  
**PI Signature** *(if multicentre trial)*

**Print name**

**Date** *(dd/mm/yy)*

\_\_\_\_\_  
**CI Signature** *(if not completing report)*

**Print name**

**Date** *(dd/mm/yy)*

If the study is sponsored by NNUH please send the completed form to [rdsae@nuh.nhs.uk](mailto:rdsae@nuh.nhs.uk) .

If the study is sponsored by the University of East Anglia and Hosted by NNUH, please scan and email the form to [researchsponsor@uea.ac.uk](mailto:researchsponsor@uea.ac.uk) and [rdsae@nuh.nhs.uk](mailto:rdsae@nuh.nhs.uk).